

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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MDL No. 01-1396 (JRT/FLN)

IN RE: ST. JUDE MEDICAL INC.  
SILZONE HEART VALVES  
PRODUCTS LIABILITY  
LITIGATION

**MEMORANDUM OPINION  
AND ORDER**

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Steven E. Angstreich, **WEIR & PARTNERS LLP**, 1339 Chestnut Street, Suite 500, Philadelphia, PA 19107; Carolyn Lindheim, **LEVY ANGSTREICH FINNEY BALDANTE RUBENSTEIN & COREN**, 10 Melrose Avenue, Suite 100, Cherry Hill, NJ 08003; Charles S. Zimmerman and J. Gordon Rudd, Jr., **ZIMMERMAN REED, PLLP**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402-4123; James T. Capretz and Tony Jensen, **CAPRETZ & ASSOCIATES**, 5000 Birch Street, Suite 2500, Newport Beach, CA 92660; Patrick Murphy, **MURPHY LAW OFFICE**, 844 East Sahara Avenue, Las Vegas, NV 89104; Joe D. Jacobson, **GREEN JACOBSON & BUTSCH, PC**, 7733 Forsyth Boulevard, Suite 700, St. Louis, MO 63105, for plaintiffs.

David E. Stanley, **REED SMITH**, 355 South Grand Avenue, Suite 2900, Los Angeles, CA 90071; Steven M. Kohn, **REED SMITH**, 1999 Harrison Street, Suite 2400, Oakland, CA 94612; Michael T. Nilan and Tracy J. Van Steenburgh, **HALLELAND, LEWIS, NILAN, & JOHNSON**, 220 South Sixth Street, Suite 600, Minneapolis, MN 55402, for defendant.

This is the third occasion that the Court has been asked to consider the class allegations in this putative class action against St. Jude Medical Inc. (“St. Jude”). On two prior occasions, the Court issued orders certifying plaintiff classes, and on both occasions the Court was reversed by the Eighth Circuit Court of Appeals. Plaintiffs have now brought a second renewed motion for certification of a class under two Minnesota consumer protection statutes. St. Jude opposes that motion and has also brought a

separate motion to strike plaintiffs' class allegations. The case is now before the Court on St. Jude's motion to strike. For the reasons given below, St. Jude's motion is granted.

### **BACKGROUND**

Plaintiffs' class allegations have been the subject of several prior orders by both this Court and the Eighth Circuit. Those orders set forth the factual background of this dispute at length, and that history is repeated only briefly below.

St. Jude produced the Silzone prosthetic heart valve. A test conducted by St. Jude showed a higher risk of paravalvular leaks at the site where the valves were implanted, and St. Jude voluntarily recalled all Silzone valves that had not yet been implanted. The plaintiffs in this action are the patients who were implanted with the valve.

Numerous lawsuits were filed across the nation, and the cases filed in federal district courts were consolidated for joint pretrial proceedings in the District of Minnesota. In 2003, the Court concluded that a class action was the appropriate method for adjudicating plaintiffs' claims under three Minnesota statutes: the False Advertising Act, Minn. Stat. § 325F.67; the Consumer Fraud Act, Minn. Stat. § 325F.69; and the Deceptive Trade Practices Act, Minn. Stat. § 325D.44. On motions by the plaintiffs, the Court issued three orders that collectively had the result of certifying two subclasses. *See In re St. Jude Med., Inc.*, No. 01-1396, 2004 WL 1630786 (D. Minn. July 15, 2004); *In re St. Jude Med., Inc.*, No. 01-1396, 2004 WL 45504 (D. Minn. Jan. 5, 2004); *In re St. Jude Med., Inc.*, No. 01-1396, 2003 WL 1589527 (D. Minn. Mar. 27, 2003). One subclass sought damages ("the consumer protection class") and the other sought injunctive relief ("the medical monitoring class"). St. Jude appealed these two class certifications, and the

Eighth Circuit reversed the certification of the medical monitoring class. *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1119-21 (8<sup>th</sup> Cir. 2005) (“*St. Jude II*”). Specifically, the Eighth Circuit found that each plaintiff’s need for medical monitoring is highly individualized. As to the consumer protection class, the circuit concluded that this Court should have conducted a more thorough choice-of-law analysis before concluding that it could apply Minnesota consumer protection law to the claims of every plaintiff. *Id.* at 1121-23.

On remand, the Court performed the choice-of-law analysis required by the Eighth Circuit, and approved a consumer protection class of “all Silzone prosthetic heart valve patients in the United States who have not undergone an explant of their Silzone valve or developed a manifest and diagnosed injury from their Silzone implant of degree or severity that would permit individual personal injury lawsuits to be commenced in their State of residence.” *In re St. Jude Med., Inc.*, No. 01-1396, 2006 WL 2943154 (D. Minn. Oct. 13, 2006) (“*St. Jude III*”). On April 9, 2008, the Eighth Circuit reversed this order. *In re St. Jude Med., Inc.*, 522 F.3d 836 (8<sup>th</sup> Cir. 2008) (“*St. Jude IV*”). This time, the circuit relied on a different ground and concluded that individualized questions about whether particular patients or doctors relied on any of St. Jude’s misrepresentations made class treatment inappropriate. The circuit also stated that individual issues would predominate at the remedial stage. While the circuit acknowledged that there were certain issues that may be common to all class-members – such as whether a published statement was materially false – it concluded that “the predominance of individual issues is such that limited class certification would do little to increase the efficiency of the

litigation.” *Id.* at 841. Ignoring the basis of its previous ruling, the circuit did not reach the question of whether it was appropriate to apply Minnesota law to the claims of every plaintiff.

Plaintiffs have now brought a second renewed motion for certification of a nationwide consumer protection class. Plaintiffs argue that their motion avoids the obstacles identified by the Eighth Circuit by (1) limiting their relief request to a refund for the cost of the valve; and (2) grounding their consumer protection claims in material omissions rather than misrepresentations. In addition to opposing that motion, St. Jude has filed a motion to strike plaintiffs’ class allegations. St. Jude’s motion to strike is now before the Court.

## ANALYSIS

### I. PLAINTIFFS’ CLASS ALLEGATIONS

#### A. Standard of Review

“Under Rule 23 the district court is given broad discretion to determine the maintainability and the conduct of class actions.” *Vervaecke v. Chiles, Heider & Co., Inc.*, 578 F.2d 713, 719 (8<sup>th</sup> Cir. 1978) (internal quotation marks omitted). Where a plaintiff’s class allegations are insufficient to satisfy the requirements for certification, the Court has authority to strike those allegations under Rule 23(d)(1)(D). *See also Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 184 n.6 (1974) (“[T]he District Court may in some instances require that pleadings be amended to eliminate class allegations.”); *see also In re Old Kent Mortgage Co. Yield Spread Premium Litig.*, 191 F.R.D. 155 (D. Minn. 2000) (striking class allegations where plaintiffs could not meet the requirements for

maintaining a class action).

## **B. Plaintiffs' Omissions Claims**

St. Jude argues that after two reversals by the Eighth Circuit, it is clear that plaintiffs cannot satisfy Rule 23, and that their class allegations should therefore be stricken. As noted above, plaintiffs respond that they now have a class definition that avoids the difficulties noted by the Eighth Circuit. They first argue that they can avoid individualized remedy issues by limiting their requested relief to a refund for the cost of the valve. Next, they argue that they can eliminate any individualized liability issues by basing their consumer protection claims on material omissions, rather than misrepresentations. Because the Court finds that plaintiffs cannot overcome the individualized liability issues now raised by the circuit, the Court addresses that issue first.

### **1. Individualized Liability**

As an initial matter, the Court notes that plaintiffs' attempt to certify an omissions class appears to have already been rejected by the Eighth Circuit. In the first renewed motion for class certification, plaintiffs argued that St. Jude violated Minnesota's consumer protection statutes by, in part, "suppress[ing] a wide array of safety and efficacy data." (Pl.'s Mem. in Supp. of Renewed Mot. to Certify Consumer Protection Class, Docket No. 409, at 5.) Plaintiffs also included a separately numbered section in their memorandum titled "Omissions are Violations," and listed twenty-four specific facts allegedly omitted by St. Jude. (*Id.*, at 5-9, 40-41.) In other words, plaintiffs' brief

made it clear that they were seeking certification of a consumer protection class based in part on St. Jude's alleged material omissions.

When this Court ruled on plaintiffs' motion, it also confirmed that material omissions were a part of the claims it was considering, by specifically noting that plaintiffs' claims are "based on alleged false representations **and material omissions.**" *St. Jude III*, 2006 WL 2943154, at \*4 (emphasis added). Indeed, the presence of these material omission claims was part of the reason that this Court was required to engage in a choice-of-law analysis, assessing whether it was appropriate to apply Minnesota law to plaintiffs from jurisdictions where consumer protection laws differ from the law in Minnesota. *Id.*, at \*5 n.4 (noting that the law in some jurisdictions differed on the question of whether material omissions are prohibited). Later, when this Court's order was appealed to the Eighth Circuit, plaintiffs again made it clear that omissions claims were a part of their motion, by specifically directing the circuit to evidence of St. Jude's "material suppression of data and other omissions." Brief of Appellee at 7 n.9, *In re St. Jude Medical Inc., Silzone Heart Valves Prods. Liability Litig.*, No. 06-3860 (8<sup>th</sup> Cir. Mar. 19, 2007). In sum, the certification motion before the circuit included the question of whether plaintiffs could maintain a class-wide consumer protection claim based on material omissions. The circuit rejected certification of the consumer protection class in its entirety, without specifying that this rejection applied solely to plaintiffs' misrepresentation claims, and without otherwise indicating that claims based on omissions merited more favorable treatment.

The Court adds that while the circuit's analysis focused more consistently on St. Jude's alleged misrepresentations, the fact that St. Jude's alleged misrepresentations and omissions were not discussed separately was not unusual in light of the similarities between these allegations. (*See* Pl.'s Mem. in Supp. of Renewed Mot. to Certify Consumer Protection Class, Docket No. 409, at 5-11.) Indeed, in many cases, plaintiffs first made omission allegations contending that St. Jude omitted test information that raised questions about the quality of the disputed valves, and then added separate misrepresentation claims challenging St. Jude's assertions that the test results had been positive. (*See id.*) In those circumstances, the omission and misrepresentation claims were effectively mirror images, and it is unsurprising that the circuit elected to discuss them together. In sum, plaintiffs' omissions claims appear to have been presented to the circuit and rejected, leaving this Court without authority to revisit the issue.<sup>1</sup>

The Court adds that even if this issue was not foreclosed by the circuit – that is, even if this Court construed the circuit's opinion as merely addressing misrepresentation claims – the Court finds little room to distinguish the circuit's reasoning.

The Eighth Circuit began its analysis by observing that “[b]ecause proof often varies among individual persons concerning what representations were received, and the degree to which individual persons relied on the representations, fraud cases often are

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<sup>1</sup> Plaintiffs also briefly argue that a recent decision by the United States Supreme Court, *Bridge v. Phoenix Bond & Indemnity Co.*, 128 S. Ct. 2131 (2008), undermines the reasoning in *St. Jude IV*. This argument is not persuasive. In *Bridge*, the Supreme Court interpreted the federal civil Racketeer Influenced and Corrupt Organizations Act (“RICO”) and a federal mail fraud statute, and concluded that reliance was not a necessary element of a RICO claim based on mail fraud. Here, however, the key statute is a Minnesota state statute, and Minnesota's Supreme Court – which, of course, has the final word on the meaning of Minnesota laws – has specifically and exhaustively explained that statute's reliance element. *See, e.g., St. Jude IV*, 522 F.3d at 838-42. Nothing in *Bridge* did, or could, impact that analysis.

unsuitable for class treatment. . . . This case exemplifies the difficulty with class treatment of cases alleging fraud or misrepresentation.” *Id.* at 838. Following this strong language, the circuit explained that individualized questions related to plaintiffs’ reliance on St. Jude’s conduct precluded certification. The circuit explained that even though **direct** evidence of individual reliance is not required in damage claims brought under Minnesota’s consumer protection statutes, “proof of a reliance component is still required,” and that this proof would likely vary among class members because of the individualized nature of St. Jude’s contact and communications with particular doctors and patients. *Id.* at 839. Finally, the circuit noted that even if plaintiffs were able to provide class-wide evidence satisfying this reliance component, St. Jude was entitled to rebut allegations of reliance with evidence that certain patients or doctors did **not** rely on St. Jude’s fraudulent conduct. *Id.*

Any question about whether the proof of reliance required in *St. Jude IV* and the accompanying obstacles to certification are relevant to omissions cases was answered in the affirmative in *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 927 (8<sup>th</sup> Cir. 2004). There, in a case also involving Minnesota’s consumer protection statutes, the circuit explained, “[a]lthough Mrs. Tuttle need not present direct evidence of Tuttle’s individual reliance, Mrs. Tuttle must establish some proof that the conduct of the smokeless tobacco manufacturers . . . in failing to warn caused consumers to continue using smokeless tobacco and to sustain physical injury in reliance on the defendants’ conduct.” *Id.* In other words, *Tuttle* applied Minnesota’s consumer protection claims in essentially the same manner as *St. Jude IV*, complete with a requirement that plaintiffs provide proof of



reliance. So long as this requirement applies in omissions cases, it is unclear why defendants would not be afforded the same individualized opportunity to rebut the reliance of particular doctors or patients recognized in *St. Jude IV*. The circuit found that this rebuttal opportunity precluded certification of plaintiffs' misrepresentation claims, and it is unclear why it would not have the same impact on a set of omissions claims that essentially challenge the same communications under a different heading.

Were this Court writing on a blank slate, it would likely conclude that plaintiffs have provided sufficient, uniform evidence to satisfy this reliance component, and that certification of an omissions class is appropriate. Prior courts have indicated that examples of evidence that may satisfy the "reliance component" include "consumer testimony and circumstantial evidence, including consumer surveys, consumer reaction tests[,] market research," and expert testimony. *Tuttle*, 377 F.3d at 927; *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2, 11-15 (Minn. 2001). Plaintiffs have submitted an affidavit from expert Eric G. Butchart opining that the omitted information was "material information that bears upon the safety of the Silzone coating." (Hedberg Decl., Docket No. 535, Ex. C., ¶ 5.) Butchart further avers that a reasonable cardiac surgeon would have considered the information "important and essential . . . in deciding whether to purchase and implant the Silzone valve." (*Id.*, ¶ 8.) This evidence would likely be sufficient to support a claim on behalf of an individual plaintiff, and if a class of plaintiffs were deprived of the same material information – regardless of whether the claim is styled as a misrepresentation claim or an omission claim – such a claim would appear well-tailored to the expedience and purposes of class-wide treatment. However,

the circuit has, at a minimum, considered misrepresentation claims that are nearly identical to plaintiffs' omission claims and found that they do not permit certification.<sup>2</sup> As noted above, these misrepresentation claims were, in many cases, essentially mirror images of plaintiffs' omissions claims. In those circumstances, and at this time, the Court simply can find no room for reaching a different result.

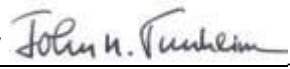
Accordingly, St. Jude's motion to strike is granted. Further proceedings related to certification of a consumer protection class are therefore unnecessary, and plaintiffs' second renewed motion to certify a consumer protection class is denied.

### **ORDER**

Based on the foregoing, all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. St. Jude's Motion to Strike Class Allegations in Plaintiffs' Second Renewed Motion for Class Certification [Docket No. 541] is **GRANTED**.
2. Plaintiffs' Second Renewed Motion to Certify Consumer Protection Class [Docket No. 533] is **DENIED**.

DATED: June 23, 2009  
at Minneapolis, Minnesota.

s/   
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JOHN R. TUNHEIM  
United States District Judge

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<sup>2</sup> The circuit also indicated that this was not a case where certification of specific issues was appropriate. *St. Jude IV*, 522 F.3d at 841.